

REVISED VERSION

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
29 July 2004 (29.07.2004)

PCT

(10) International Publication Number
WO 2004/062651 A1

(51) International Patent Classification⁷: A61K 9/72, 39/39

(21) International Application Number:
PCT/GB2004/000104

(22) International Filing Date: 14 January 2004 (14.01.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0300885.1 15 January 2003 (15.01.2003) GB

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

(88) Date of publication of the revised international search report: 30 September 2004

(15) Information about Correction:
see PCT Gazette No. 40/2004 of 30 September 2004, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PHARMACEUTICAL AEROSOL COMPOSITION

(57) Abstract: An aerosol formulation comprising a biodegradable microsphere comprising a non-living reagent, such as a sub-unit vaccine, that produces a protective immune response in a mammal to whom it is administered. Nebulizers and inhalers containing such formulations are also described and claimed.

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Rec'd PTO 15 JUL 2004

7542449

INTERNATIONAL SEARCH REPORT

Inter: Application No
PCT/GB2004/000104

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/72 A61K39/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|---------------------------------|
| X | <p>WO 02/43705 A (UNIV FLORIDA) 6 June 2002 (2002-06-06)</p> <p>page 3, line 35 - page 4, line 14 page 4, line 17 - line 39 page 5, line 11 - line 27 page 11, line 45 - page 12, line 38 page 13, line 8 - line 21 page 13, line 25 - page 14, line 6 examples claims</p> <p>----- -/--</p> | <p>1,2, 6-11, 14-17</p> |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
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- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

2 June 2004

Date of mailing of the international search report

28. 06. 2004

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Epskamp, S

INTERNATIONAL SEARCH REPORT

 Intern Application No
 PCT/GB2004/000104

| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|--|--|-----------------------|
| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | EYLES J E ET AL: "Protection studies following bronchopulmonary and intramuscular immunisation with Yersinia pestis F1 and V subunit vaccines coencapsulated in biodegradable microspheres: a comparison of efficacy" VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 18, no. 28, August 2000 (2000-08), pages 3266-3271, XP004205869 ISSN: 0264-410X | 1-11, 14-17 |
| Y | abstract paragraphs [02.2], [02.3] paragraph [0004] | 1-17 |
| X | ----- EYLES J E ET AL: "Analysis of local and systemic immunological responses after intra-tracheal, intra-nasal and intra-muscular administration of microsphere co-encapsulated Yersinia pestis sub-unit vaccines" VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 16, no. 20, 1 December 1998 (1998-12-01), pages 2000-2009, XP004138449 ISSN: 0264-410X | 1-11, 14-17 |
| Y | abstract page 2001, right-hand column, last paragraph - page 2002, left-hand column, paragraph 1 page 2002, right-hand column, last paragraph page 2003, right-hand column, paragraph 5 page 2008, right-hand column | 1-17 |
| Y | ----- WO 01/70200 A (SECR DEFENCE ; ALPAR HAZIRE OYA (GB); EYLES JAMES EDWARD (GB); WILLIAM) 27 September 2001 (2001-09-27) page 4, line 14 - page 5, line 3 examples claims | 1-17 |
| X | ----- WILLIAMSON E D ET AL: "Local and systemic immune response to a microencapsulated sub-unit vaccine for plague" VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 14, no. 17, 1 December 1996 (1996-12-01), pages 1613-1619, XP004016821 ISSN: 0264-410X abstract page 1614, left-hand column, paragraph 4 - right-hand column, paragraph 4 ----- -/-- | 1-11, 14-17 |

INTERNATIONAL SEARCH REPORT

Inter: Application No
PCT/GB2004/000104

| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|--|--|------------------------|
| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | <p>EYLES J E ET AL: "Microsphere translocation and immunopotential in systemic tissues following intranasal administration" VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 19, no. 32, 14 September 2001 (2001-09-14), pages 4732-4742, XP004303168 ISSN: 0264-410X abstract paragraph [02.4]</p> <p>-----</p> | <p>1-11, 14-17</p> |

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/GB2004/000104

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 17 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Inter application No
PCT/GB2004/000104

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
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